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Evidence based Uncertainty analysis: What should we now do in Europe?-A view point

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Abstract

There has been a great deal of discussion regarding both the communication of scientific uncertainties associated with regulatory decisions as well as the supposed need for more transparent uncertainty analyses associated with risk assessments themselves. More recently in Europe this discussion has been led by the European Food Safety Authority's Scientific Committee. In this view point we both review the ongoing debates surrounding uncertainty analysis as well as discuss some of the problems associated with communicating uncertainties. In the final section of the view point we offer some recommendations regarding what EFSA could do now going forward.

Key words: uncertainty analysis, transparency, EFSA

1. Introduction

There has been a great deal of recent discussion regarding both the communication of scientific uncertainties associated with regulatory decisions as well as the supposed need for more transparent uncertainty analyses associated with risk assessments themselves (e.g. EFSA 2015c; Fischhoff and Davis 2014). With regard to the communication aspect we agree with Fischhoff and Davis who note:

> "Communicating uncertainty requires identifying the facts relevant to recipients' decisions, characterizing the relevant uncertainties, assessing their magnitude, drafting possible messages, and evaluating their success. Performing these tasks demands commitment from scientists and from their institutions." (Fischhoff and Davis 2014, p.13670)

In other words communicating scientific uncertainty is not a task to be underestimated. Similarly with regard to being more transparent with uncertainty analyses we find EFSA's definition useful:

> "Uncertainty is defined as referring to all types of limitations in the knowledge available to assessors at the time an assessment is conducted and within the time and resources available for the assessment." (EFSA 2015c, p. 3)

In this paper we provide an overview of what is needed to develop an evidence-based uncertainty analysis in Europe. A large amount of our discussion will focus on the European Food Safety Authority (EFSA) as it is the first European regulatory agency that has developed a draft in-depth guidance document on the topic (EFSA 2015c; EFSA 2016a.

2. Background

In the summer of 2015 the European Food Safety Authority (EFSA) put forward a draft guidance document on uncertainty analysis for public commentary. The stated aim of the Agency is that once the guidance document is approved that:

> "…uncertainty analysis will be unconditional for EFSA panels and staff and must be embedded into scientific assessment in all areas of EFSA's work." (EFSA 2015c, p.1).

The guidance document provides a rigorous overview of both how to understand uncertainty as well as how to integrate it with scientific advice as robustly as possible. The publication of this document as

well as the further updated draft guidance following public consultation (EFSA 2016a) should not come as a surprise. Already back in 2005 EFSA suggested that within the risk assessment context greater transparency was needed and as part of that the underlying scientific uncertainties should be described (EFSA 2005; Van Asselt et al 2009). Similarly, in 2006 EFSA's Scientific Committee considered publishing some form of qualitative evaluation of uncertainty (EFSA 2006; Spiegelhalter and Riesch 2011). In 2011 Flari and Wilkinson submitted a scientific report to EFSA on the harmonization of the terminology used in EFSA's scientific opinions including uncertainty (Flari and Wilkinson 2011). This was reinforced in EFSA's Scientific Committee meeting in July of 2012 when one of the concrete outcomes was to continue the Agency's work on uncertainty (EFSA 2016b). Finally, EFSA held a targeted consultation between 10th November 2014 and 10th February on an editorial written by EFSA scientists published on EFSA's Journal pages on the making of "Open EFSA" including the development of a guidance document on uncertainty analysis (EFSA 2015b; Hardy et al 2015).

From an academic perspective there is much here that is commendable. There have been a few guides on uncertainty analysis in the past (including Cooke 1991; Cox and Baybutt 1981; Cullen 1999; Cullen and Frey 1999; Morgan and Henrion 1992; Thompson and Graham 1996) and from a communication perspective there is still some confusion on how to best do it (e.g. Bostrom et al 2015; Fischhoff 2015; Fischhoff and Davis 2014; Joslyn and LeClerck 2013; Keohane et al 2014; Thompson 2002). It is also a topic that has warranted plenty of research over the last couple of years (eg Lidskog and Sjodin 2016; Lindaas and Pettersen 2016; Poortvliet and Lokhorst 2016; Wardman and Mythen 2016). So an in-depth discussion on the topic by a European regulatory agency is therefore welcome.

That said, from a policy perspective attaching uncertainty analysis to scientific opinions will show how complex some scientific judgments are and that there is often an element of uncertainty which does not, however, invalidate the conclusions. This in turn may not only lead

to a reduction in confidence of the scientific judgments by those non-scientists who have been asked to interpret the judgment: namely policy makers, regulators and stakeholders (see Johnson and Slovic 1998 for a discussion). In addition it may lead to the questioning of the risk analysis model used in developing regulations as initially conceived by the US NRC in 1983 (US NRC 1983). As one critic of the risk analysis school argued:

> "Numerous scholars have provided detailed evidence showing that the only reason why regulatory policy-making institutions were able to portray their policy-making processes with technocratic or decisionist models (ala US NRC 1983) was because they contrived to construct representations of the scientific aspects of risk in narrow consensual terms, and by selectively understating and concealing the uncertainties and concealing key non-scientific assumptions" (Millstone 2007, p.497).

This raises several important questions for risk regulators and communicators. What is the most likely policy outcome of such a reduction of confidence (if any) in a scientific judgment? In addition, are there cultural differences? Are citizens in some member states more tolerant of scientific uncertainties than others? Does it vary between Agencies themselves? The answers to these questions are presently unclear. Arguably in a number of cases some stakeholders and critical academics would push for policy makers and regulators to move from an evidence based and risk informed approach to policy making to one based on hazard and the precautionary principle (e.g. see EEA 2001 and 2013; Jasanoff 1987 and 1990; Millstone 2007). In so doing EFSA's initial and updated guidance documents on uncertainty may un-intentionally undermine the Authority's ability to provide science based and risk informed advice to the risk managers, a task it was set up to do.

The initial draft guidance document on uncertainty analysis was out on public consultation between 18th June and 10th September 2015. The consultation led to 288 comments from 33 different parties. Based on these comments EFSA revised the draft guidance document

and it was published in March 2016 (EFSA 2016a). The revised document on uncertainty analysis will now be used during a one year trial period by all of EFSA's Scientific panels (EFSA 2016a and c). Following the trial period EFSA aims to finalize the guidance document by the end of 2017. Ultimately EFSA takes the view that being more transparent about uncertainties in their scientific opinions will:

> "enable citizens to contribute more widely to its (EFSA's) risk assessment work and thereby to increase trust." (EFSA 2015c, p. 11).

The aim of this viewpoint is to provide advice for EFSA and other European agencies which are contemplating to put forward similar uncertainty guidance documents on ensuring that these documents remain evidence based and risk informed as possible. The paper itself is based in part on 51 interviews with policy makers and regulators active in the Dutch Government, European Commission, Irish Government, Swedish Government, UK government and various European regulatory agencies.

3. Uncertainty: A review of the ongoing debates in risk analysis

EFSA's 2015 initial draft guidance document as well as the 2016 revised draft presents a strong case for paying more attention to uncertainties, including listing uncertainties and their sources. As EFSA's mandate is primarily to conduct risk assessment on behalf of the European Union, and DG SANTE in particular, the Agency's views on the relationship between risk and uncertainty may have a range of implications: Is uncertainty analysis a way of making sure that scientific uncertainties are captured by risk assessments? Or does the proposed uncertainty analysis constitute a 'paradigm shift'?

The ISO 31000 (2009)/ISO Guide 73:2002 defines risk as the 'effect of uncertainty on objectives.' A view commonly held in both academic and regulatory circles is that understanding and managing the effects of such uncertainties usually involves an estimate of likelihood and impact (Aven 2012a and b; Aven and Renn 2009).

Risk has commonly been defined as combination of the likelihood of an occurrence if a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure (s) (Knight 1921; OHSAS 18001: 2007; Renn et al 2011). The seminal 'Red Book' of the US National Research Council (NRC 1983) suggested a step-by-step method to deal with uncertainties that would essentially entrust risk assessments to natural scientists. More recent efforts to normalize risk frameworks at the international level (e.g. IRGC 2005) are broadly consistent with this approach (Bouder et al 2007).

The 'classic' conception of risk that underpin these perspectives is far from consensual, however. In particular it does not capture the views of those who 'advocate more subjective degrees of beliefs about the uncertain future ' (Bernstein 1998, p.6). There are a number of different and to certain degree competing strands of risk analysis that one needs to consider including risk assessments, uncertainty analyses, risk perceptions, the precautionary principle, risk management and decision making under uncertainty (Aven 2010). Qualitative and quantitative measures of uncertainty are proposed and argued for, where the use of probability to measure uncertainty has a dominating position (Apostolakis 1990). In the discussion about principles to consider and communicate uncertainty, some even advocate seeing beyond probability to represent uncertainty in risk assessment contexts (Flage et al. 2014; Ferson and Ginzburg 1996; Mosleh and Bier 1996; Walley 1996).

A central question that uncertainty analysis therefore raises is whether it should be recast as a way to 're-negotiate' or 'reframe' the role of science (Callon et al 2009; Levidow 2001; Macnaghten et al 2005) to reflect the subjectivity or 'social construct' of the scientific process. These critics of conventional 'reductionist' risk assessment have developed three main arguments to seek new approaches:

3.1
A first argument is about the inadequacy of conventional science to capture emerging risks. In other words, to Wynne, risk assessment

was originally used as a way to analyse well-defined problems (Wynne 1992). With the move to what he calls ‘extensive problems’ such as environmental systems on a global scale (such as climate change) the conventional scientific approach to cause-effect relationships excludes complexity and ambiguity and therefore discards uncertainties before they have been investigated. In this context uncertainty analysis should focus on what has been selected to count as scientific evidence (van Asselt 2005). More recent research developments suggest that uncertainty should be understood as that which emerges from negotiations about the adequacy and relevance of current knowledge (Hermans 2015).

3.2

The second argument is about the limits of quantification. Uncertainties, it is argued, create problems that are fundamentally qualitative, which means that quantifications and more knowledge will not necessarily reduce uncertainty (Klinke and Renn 2002; van Asselt 2000; van der Sluijs 2012; Walker et al 2003). In this context uncertainty analysis should be developed in a fashion to introduce more qualitative analysis as a way to complement conventional quantitative studies.

3.3

The third main argument is that conventional science excludes relevant dimensions such as moral and ethical deliberations. Uncertainty analysis is typically conceptualized as a way to inject more deliberation into the decision making process. Two illustrative examples include the study *Rational Analysis for a Problematic World: Problem Structuring Methods for Complexity, Uncertainty and Conflict* (Rosenhead 1989) and the large study *Uncertainty and Quality in Science for Policy* (Funtowicz and Ravetz 1990). Both studies plead for new modes of balancing scientific uncertainty and societal challenges that have historically been addressed by science through opening up to more relevant approaches and involving practitioners and stakeholders to a greater degree (e.g. see Liberatore and Funtowicz 2003).

4. Uncertainty analysis and risk communication

Arguably, the debate about the role of uncertainty has focused primarily on the adequacy of "old" (that is US NRC 1983) approaches for dealing with uncertainty, especially in the context of new emerging 'uncertain' risks (Van Asselt and Vos 2006 and 2008). One aspect that is largely overlooked, however, is that of the implications of uncertainty analysis for institutional risk communication. According to the NRC 1983 report, societal input and risk communication would essentially be needed before and after risk assessment, as well as at the risk framing and management stages. On the other hand, risk assessment itself would be entrusted to scientists. The question is whether the NRC 1983 or subsequent updated models which argue for more effective participative decision processes (US NRC 1989; 1996; 2009) can prevail today (for a lengthy discussion see Poortvliet and Lokhorst 2016).

EFSA takes the view that by conducting uncertainty analysis in a transparent fashion that this will enable greater citizen involvement in the Authority's risk assessment work leading to increased public trust as well as other non-communication related benefits (EFSA 2015c). As EFSA notes in its initial guidance document:

> "From EFSA's organizational perspective, communicating scientific uncertainties is crucial to its core mandate, reaffirming its role in the scientific assessment process. The clear and unambiguous communication of scientific uncertainty is an enabling mechanism, providing decision-makers with the scientific grounds for risk-based decision-making. It increases transparency both of the assessments and of the resulting decision-making, ensuring that confidence in the scientific process is not undermined." (EFSA 2015c p. 62)

EFSA's view is shared by others. The US National Research Council in an earlier study argues that the US EPA should be more informative in its communication of risk including communicating uncertainty (US NRC 1994) and in 1995 the Administrator of the US EPA argued that

> "a balanced discussion of reasonable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment." (Browner 1995).

In 2006 the US NRC concluded that the US National Weather Service should not only communicate the expected weather but also the uncertainties surrounding weather forecasts themselves (US NRC 2006) a view that is supported by some academics (e.g. Joslyn and LeClerc 2013). In 2009 the US NRC once again encouraged the EPA to be more open regarding scientific uncertainties noting that:

> "EPA should encourage risk assessments to characterize and communicate uncertainty and variability in all key computational steps of risk assessment…" (US NRC 2009, p. 7)

The Intergovernmental Panel for Climate Change (IPCC) also understood the importance and associated difficulties of communicating uncertainty (Moss and Schneider 2000).

On the whole it appears that policy makers and regulators should be communicating more rather than less uncertainty. It is clear, for example, had policy makers been more transparent regarding the real scientific uncertainties associated with the link between BSE (mad cow disease) and Variant CJD in humans then it is likely that the public's trust in the Ministry of Agriculture Food and Fisheries (MAFF) would not have declined the way it did (Eldridge et al 1998; Jasanoff 1997).

Some academics take the view that one should communicate uncertainty no matter how complex the issue is be it a food or a public health scare. There are a number of reasons why such communication is needed. Firstly, the public is on the whole much more competent than what experts make them out to be (see Jasanoff 1993; Wynne 1989 for a detailed discussion). In addition, if the authorities are not as transparent as they could be and prefer providing simple, more easily digestable messages, they could be accused of not telling the truth (Phillips Report 2000; Wynne 1996). As Frewer et al argue:

> "People are more accepting of uncertainty associated with the scientific process of risk management than a lack of action or

> lack of interest on the part of the government…It is suggested that people want transparency in risk management and to be able to make informed choices about exposure to food risk. All information about uncertainty should be available in the public domain, together with the means for consumer decision-making…" (Frewer et al 2002, p.371; see also Hunt and Frewer 2001).

Or as Lord Robert May, a former Chief Scientific Advisor of the UK Government, argued:

> "You can see the temptation on occasion to wish to hold the facts close so that you can have internal discussion and the formation of a consensus so that a simple message can be taken out into the market place. My view is strongly that the temptation must be resisted, and that the full messy process whereby scientific understanding is arrived at with all its problems has to be spilled out into the open." (Robert May 2000, quote taken from the Phillips Report 2000, Vol.1, p.265.

In addition, past studies show that publics are able to interpret and understand explicit quantitative expressions of uncertainty (Fischhoff 2012) although this has been questioned by others who point out (at least in the United States) that nearly a fourth of the public may be innumerate and thus less able to understand quantitative expressions of uncertainty, and more susceptible to framing effects and other interpretive biases (see Peters and Levin 2008; Peters et al 2007).

In sum, a number of regulators, policy makers and academics have shown that communicating uncertainty is a good thing as it can lead to public trust in the Agency in question and in greater public/stakeholder understanding of the broader decision making process.

Above we have discussed some of the reasons why one should communicate uncertainty. There are also problems with communicating uncertainty to a greater degree and these are discussed in the next section.

5. Some problems associated with communicating uncertainties

There are in effect three issues: a) Not all empirical studies show that communicating more scientific uncertainty leads to more trusting and more informed publics. Some show that there can be unwanted, counter-intuitive and even reverse effects. B) By increasing transparency about the underlying scientific uncertainty may make it more accessible for misuse and or abuse; and C) Does the Agency actually need to communicate greater scientific uncertainty considering the issues raised in (A) and (B) and the potential trade-offs (such as these types of communications will be resource intensive).

5.1 Empirical studies

A number of studies have examined whether communicating uncertainties leads to more informed and trusting citizens, or on the other hand, to more confused and distrusting ones (Jensen et al 2016). Similar to the calls for greater transparency, the call for the communication of greater uncertainty may be a new "mega trend" that simply will not go away (Pierson 2004). On the whole citizens, just as they do with transparency, will welcome greater uncertainty analysis if asked in surveys. They will not want to be perceived as being ignorant (Fisher 1993). That said, beyond this finding the jury is out whether communicating scientific uncertainty is helpful or harmful in the eyes of the public. In some cases, for example, when people expect the communication of uncertainty, such as with regard to weather warnings, they will very much welcome it (Joselyn and LeClerc 2013). On the other hand, on a day-to-day basis people want to feel certain (Rabinovich and Morton 2012). When they do not feel certain they develop different forms of coping mechanisms to help them to become certain again (see for example Festinger 1957; Nowotny 2016; Poorvliet and Lokhorst 2016).

Reading the peer review literature we take the view that overall the public will have a difficult time processing information about uncertainty. There are a series of studies that support this belief.

Johnson and Slovic, for example, in a number of studies indicated that:

a) A large number of respondents would not welcome uncertainty estimates and would prefer being simply told whether a substance is safe or unsafe;
b) Discussing uncertainty estimates led to respondents to question the competency of the government agency in question;
c) A number of respondents felt that government agencies were dishonest when discussing uncertainty estimates and others became confused regarding the use of array of numbers to measure uncertainty (see Johnson and Slovic 1994; 1995, 1996; 1998)

Johnson and Slovic conclude one of their papers by noting:

> "Uncertainty is a fact of life, but life goes on: similarly, citizens expect government action on pollution in spite of uncertainty, and may suspect the topic of uncertainty is being raised merely to justify inaction." (Johnson and Slovic 1998, p. 277)

They also found that 65 per-cent of their sample took the view that when scientists disagreed on their findings regarding certain environmental health issues these same individuals would assume "the worst case is true, just in case" (Johnson and Slovic 1998, p.272). This is corroborated by research findings that show providing any type of uncertainty information will lead individuals to see the issue or hazard to be riskier (Camerer and Weber 1992; Einhorn and Hogarth 1985). This scientific finding makes sense considering that a number of psychologists point out that the so called "negativity bias" is the main characteristic of how humans process information (Rozin and Rayzman 2001; see also Siegrist and Cvetkovich 2001). Individuals, in other words, are averse to ambiguity and prefer certainty.

Other studies show that displaying uncertainties and probabilities lead to greater risk aversion as people tend to dislike making decisions based on incomplete scientific information (Frisch and Baron 1988; Health and Tversky 1991). Such findings were also found in a study by Powell et al who argued:

> "perceived risk uncertainty is strongly associated with negative emotions such as worry and anger and, to a lesser degree, reflects a sense of not knowing (Powell et al 2007, p.339).

In addition the Presidential Commission on Risk Assessment and Risk Management took a similar view arguing that providing a range of probabilities could lead members of the public who are not used to see quantitative methods to misunderstand them (US Presidential Commission 1997), something that since then has been confirmed by Peters and colleagues (Peters and Levin 2008; Peters et al 2007).

Finally, Miles and Frewer (2003) found that communicating uncertainty regarding certain hazards to the public may lead to increased perceived risk associated with those hazards. As the authors argue:

> "…under circumstances where people feel that they have little personal control over their exposure to genetic modification and pesticides, and when those social institutions that are perceived to be in control of protecting the public indicate that there is uncertainty, the hazards may appear to be 'out of control', which results in greater perceived seriousness of the associated risks…" (Miles and Frewer 2003, p. 280)

These findings should not be seen as surprising. With regard to developing wider transparency policies within the pharmaceutical area, similar results have been observed. That is that although academics and regulators welcome greater transparency measures, and even though publics are all for it, putting large quantities (sometimes in the hundreds of thousands pages) of raw scientific data in the public domain leads to confused and upset publics and patients. In some countries, most notably Germany and Spain, more than 50 per cent of the public interviewed noted that if their medicine was found on some kind of website as possibly risky they would stop taking it, going against the advice put forward by the regulators themselves (Bouder et al 2015; Chakraborty and Lofstedt 2011; Lofstedt and Bouder 2014; Lofstedt and Way 2016; Lofstedt et al 2016; Way et al 2016).

5.2 The misuse of scientific uncertainty

Experts who attempt to be honest about their scientific uncertainty calculations when advising decision makers should be praised for doing so. Only by being honest can decision makers grasp the true uncertainty behind the numbers that have been presented to them (Fischhoff 2012; Keohane et al 2014). The issue, however, is that not all interest groups are honest with regard to the communication of scientific uncertainty. In certain cases when scientific uncertainties are highlighted it can be comparatively easy for vocal partisan or economic interest groups to sow confusion and doubt. Depending on the issue itself partisan interest groups have either sought or delayed policy decisions citing scientific uncertainty. A case in point is that of challenging tougher regulations to combat climate change, in which interest groups have argued that the science behind climate change is not conclusive (Aklin and Urpelainen 2014; Dunlap and McCright 2011; Freudenburg et al 2008; Michaels 2008; Oreskes and Conway 2010; Pidgeon and Fischhoff 2011), commonly referred to as "paralysis though analysis." Another case in point is the call by certain interest groups or member states governments (such as Sweden) for a ban of endocrine disrupters in Europe, citing the precautionary principle, with reference to the scientific uncertainty on the topic (Lofstedt 2015). As a number of EFSA's scientific opinions are already heavily debated by partisan minorities such as on the safety of GMOs and whether or not to ban neonicotinoid pesticides (Alemanno 2013) the chances are great that publishing uncertainty analysis along-side the scientific opinion will create interest among these groups in using the uncertainty analyses out of their proper context intentionally or unintentionally to create further doubt and confusion.

5.3 Is there a greater need to communicate more scientific uncertainty?

One of the key drivers why EFSA is promoting further uncertainty analysis, as part of the publication of its scientific opinions, is the assumption that this will increase public trust (EFSA 2015c and e). Doing so fits with EFSA's agenda to become more transparent (Way and Lofstedt 2016). Already at the time of establishing EFSA the European Commission argued:

> "In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data." European Commission 2002, p. 2)

Publishing uncertainty analyses together with the Agency's scientific opinions is from this perspective viewed as a further step in opening up EFSA making it more transparent (e.g. see EFSA 2014) where the primary driver is on "publishing as much information as possible" (EFSA 2015a). For example, communicating more information on uncertainty is in line with EFSA's Warehouse Project which EFSA's Executive Director, Bernard Uhl notes:

> "Our scientific data warehouse project, which we will develop over the next three to four years, will open as much as possible our treasure drove of data to be used and re-used for other purposes by other people in Europe. This will contribute to scientific progress." (EFSA Press release 2015a).

The key question is whether a move for greater transparency will actually increase public's trust toward the Authority itself assuming, of course, that EFSA's opinions remain of high quality and thus deserve trust. One can understand that when EFSA was established in 2002 greater transparency in the food risk assessment process was needed, considering the fact that the Agency was founded in the aftermath of the European BSE crisis when there was not much trust in the food regulatory system (Byrne 2014; European Commission 2000 and 2001; Lofstedt 2003). Opinion polls show that after the BSE scare no more than 12 per cent of the citizens trusted their national regulators (Pollack and Shaffer 2009). Things have changed dramatically since then. In 2010 a Eurobarometer study found that EU citizens had a high level of trust in national and European food safety agencies as sources of information regarding food scares. Studies indicate that 64% of the public trusted agencies such as EFSA to provide accurate information considerably higher than in 2005 (Eurobarometer 2010).

In addition, historically EFSA has had a rather good record in handling food alarms ranging from aspartame to semicarbazides in baby food (Gassin and van Geest 2006; Lofstedt 2008 and 2010; O'Rourke 2014; Wardman and Lofstedt 2008). This was also confirmed in the Paeps report which noted that EFSA was not only handling its communication activities better than past European based risk assessment bodies, but it was also delivering high quality scientific opinions (Paeps Report 2004). These success stories had a positive impact on the European publics themselves. Between 2003 and 2007, for example, there was an increase in the number of European citizens who said that the EU was doing a good job with regard to 'ensuring that the EU performs rather well on ensuring that agricultural products are healthy and safe' going from 39 to 45 percent (European Union 2004 and 2008; for a discussion see Klintman and Kronsell 2010). In sum, EFSA had a very competent communication department at the time (Wardman and Lofstedt 2008).

What has changed since EFSA's early years, however, is the greater politicization of food regulation in Europe. With regard to EFSA this has to do with the Agency's rather pro stance on GMOs and the never-ending discussion on the safety or risks associated with endocrine disrupters (such as Bispehnol A) (see for example EFSA 2008, 2010, 2012; Van Asselt and Vos 2008). What the GMO dispute showed was how a broad coalition could be formed-composed of anti-globalization activists, organic farmers, consumer groups and environmentalists-to start a campaign to halt the introduction of GM crops to Europe (Vogel 2012).

Further complicating matters is the growing debate surrounding conflicts of interest which in part originated from NGO investigations revealing that a number of the academics who had served (and continue to serve) on EFSA's scientific panels providing advice on GMO related policies also had some form of ties to the food industry (Robinson et al 2013). This led NGOs to question the legitimacy of EFSA (e.g. CEO 2012). As the Corporate European Observatory noted:

> "Too often it's not independent science that underlies EFSA decisions about our food safety, but industry data. EFSA panels base their scientific opinions on risky products like pesticides and GMOs largely on industry-sponsored studies. EFSA has often been found to ignore independent research for unscientific reasons. The agency has issued controversial guidelines for the assessment of pesticides and GMOs that benefit industry, not the public interest. In some cases EFSA even copies wording from industry sources." (CEO 2012, p.3)

These types of attacks will not go away with increased transparency or by putting uncertainty analyses in the public domain. On the contrary recent theoretical and empirical research shows that it is almost inevitably going to get worse (Mason and O'Neill 2007). To date the groups that have consistently been pushing EFSA to promote greater transparency (and thereby also uncertainty analysis) are the NGOs themselves. They in turn have continued to use the data that they "mine" from the various transparency measures that EFSA have put forward against the Authority itself (e.g. CEO 2012; Robinson et al 2013). As Baroness Onora O'Neill has argued in the past:

> "Transparency requirements can benefit expert 'outsiders' by enabling them to access information about the performance of institutions and their office holders. This is particularly helpful to expert critics of government, business and professional performance. Expert critics often have the time and ability to grasp and use information in ways the wider public does not. Transparency is therefore particularly useful to the media and to campaigning organizations which can discover information that bears on others' performance (while they themselves are generally exempt from the like transparency requirements)." O'Neill 2006, p. 88).

In addition, being more open to uncertainty analysis may lead to academics critical of the dominant risk analysis model to question the need for evidence-based and risk-informed policy making itself (e.g. Millstone 2007). Similarly, advocating greater openness can be perceived as a threat by members in the broader risk assessment community who work with EFSA (Bijker et al 2009).

EFSA's Scientific Committee is aware of these criticisms as they were raised by a number of organisations at the time of the 2015 public consultation. In response to them the Committee noted:

> "The Scientific Committee acknowledges the tension identified by the commenter, between the fundamental need for transparency and the closer scrutiny this brings to the decision-making process. This is not an argument for limiting transparency of the scientific assessment but for improving the quality of both assessment and communication, and improving the transparency and communication of the decision-making process, including justification for the trade-offs made by decision-makers between benefits, risks and uncertainties…" (EFSA 2016b, p. 22)

In other words the Scientific Committee takes the view that these concerns can be overcome by simply becoming better—which will most likely require greater resources, something that Fischhoff and Davis have noted previously (Fischhoff and Davis 2014).

6. How can uncertainty analysis lead to hazard based regulation?

Uncertainty relates to a lack of knowledge and the difficulty to predict future events, outcomes and consequences (Hermans 2015; Van Asselt 2000). Calls over time for new forms of uncertainty analysis stem from the perception that the so called modern 'risk society' creates different even greater more unpredictable risks (Beck1992). In this context, conventional scientific methods for risk assessment have been portrayed for over 30 years as flawed (Jasanoff 1990; Jasanoff and Wynne 1998; Millstone et al 2008) on the basis that risk assessments are socially and politically biased, and used as a tool by industry to promote certain products (e.g. Michaels 2008). To make matters worse these same critics take the view that risk assessment is a technique to examine well-defined problems. When it comes to modern day environmental issues-be it the regulation of endocrine disrupters or combatting climate change-then decision makers are dealing with either ordinary scientific uncertainty or great scientific uncertainty (Arrow et al 1996; Faucheux and Froger 1995; Hansson 1996). In these circumstances scientific approaches focusing solely

on cause and effect relationships, of which risk assessment is a part, is considered as simply not working. Rather what happens is the development of a so called 'post-normal' type of system where 'typically facts are uncertain, values in dispute, stakes high and decisions urgent' (Funtowicz and Ravetz 1991 and 1993; Funtowicz 2001). It is in these types of post normal environments when the precautionary principle can, and where many of its proponents argue that it should, be used (e.g. European Environment Agency 2001 and 2013; Tallacchini 2014). In sum, proponents of the precautionary principle argue that the use of risk analyses methodologies as defined by the US National Research Council (that is risk assessment, risk management and risk communication) and implemented by bodies such as OECD and member states throughout Europe, most notably the Netherlands and the UK, are simply outdated and are no longer of any use in the modern day environment (Millstone 2007).

By EFSA arguing for adding uncertainty analysis to scientific opinions this opens the door to scientists and campaigners who see the recognition and discussion of uncertainties as further evidence that the Agency is working on 'post normal' science issues and that therefore the precautionary principle needs to be more often invoked.

EFSA' Scientific Committee was aware of these concerns and when they were raised by a number of commentaries the Committee noted:

> "The Precautionary Principle is a matter for decision makers, not assessors, so detailed discussion of its meaning, relevance and application are outside the scope of EFSA's Guidance. Decisions on the application of the precautionary principle require consideration of the degree of uncertainty, information on which will be improved by the approaches in the draft Guidance. The Guidance therefore contributes to improving the consideration and transparency in the decision-making process and reduce, rather than increase, the issues which commentaries are concerned about." (EFSA 2016b, p. 21)

In other words EFSA takes the view that their Guidance document, when finalized, will reduce the unscientific application of the precautionary principle (see Lofstedt 2014b for a discussion).

7. What do we need to do now going forward?

EFSA and other European agencies are committed to developing some form of uncertainty analysis (eg ECDC 2016). This topic will simply not go away, especially not as there is so much support for it from highly esteemed institutions such as the US National Academy of Sciences and other bodies (ECDC 2016; US NRC 2009). That said, the question that has to be asked is what is now needed to promote evidence-based uncertainty analysis in Europe? There are a number of recommendations that should be considered.

7.1 **Conduct research evaluating EFSA's uncertainty analysis communications.**

All forms of communications put forward by regulatory agencies need to be pretested and evaluated so as to find out if messages and communication programs actually have their intended effect (Fischhoff et al 2011). More often than not risk messages put forward by European regulatory agencies are neither pretested nor properly evaluated. Past studies show, for example, that the European Medicines Agency were unaware what effects their calls for greater transparency in the pharmaceutical area would have on the public and or patients (Bouder et al 2015; Lofstedt and Bouder 2014). This principle also applies to attaching uncertainty analysis to scientific opinions. There is a need to get a clear idea as soon as possible of how the public and other stakeholders will view this new approach. Will the public broadly welcome them, or will it be more distrustful of science and the Agencies that promote them? At present time this is unclear. As Fischhoff et al (2011) discuss this research could be anything from low to medium to high cost depending on how accurate an understanding EFSA wants on the impacts of its uncertainty analysis communications. Considering this review, it seems that a lot is at stake for EFSA. We therefore welcome EFSA's recent decision to fund an independent research project:

> "to test messages and establish best practice for communicating scientific uncertainties to recipients of EFSA's scientific advice (e.g. decision-makers, media, public) (EFSA 2016c).

7.2 Promoting evidence based uncertainty

In order to prevent an 'over-precautionary bias', uncertainty should be seen as an integral part of risk and should be assessed and managed through a 'risk handling chain' modelled on the NRC's seminal document *Risk Assessment in the Federal Government: Managing the Process* (US NRC 1983) . In so doing, uncertainty analysis should be part of the risk assessment process and seen as a tool for policy makers and regulators (risk managers) to better understand how much certainty (or uncertainty) there is in the underlying scientific opinions making up the risk assessment itself (EFSA 2016b; US NRC 2009). In such a scenario, uncertainty analysis should not be viewed as another tool in the larger transparency tool box but as an integral part of risk assessment.

7.3 Scientists need to become better communicators of uncertainty.

At present scientists are overall poor communicators when it comes to scientific uncertainty (Budescu et al 2009; Fischhoff and Davis 2014). Hence, uncertainty analysis should not be pursued as a goal on its own, but rather, in the context of more general training of scientists in the area of risk communication.

7.4 EFSA needs to avoid falling in the trap of "path-dependency"

To date EFSA has spent more than 10 years trying to develop better uncertainty guidance to their scientific opinions. For this the Agency should be commended for. The Agency needs now, however, to be careful that it does not fall into the trap of "path dependency" (Pierson 2004). That is to say as the Agency now has spent some more time and resource in developing guidance on uncertainty, and with certain academics and advisors with the Scientific Committee having spent more or less their entire careers working in this area, the Committee may have a difficult time to reverse course should the testing of uncertainty analysis messages on the public lead to unfavorable results. This is all the more worrying considering that the Scientific Committee is at times using rather loaded language in defending its position noting for example in its revised uncertainty guidance that:

> "…communicating scientific uncertainties is crucial to its core mandate, reaffirming its role in the risk analysis process. There is a moral obligation to be open and transparent to the public." (EFSA 2016a, p.102)

7.5 There is a need to broaden the discussion on uncertainty analysis

To date EFSA has done an admiral job reaching out to other regulatory bodies and agencies on the work they are doing on uncertainty analysis such as arranging a workshop on the topic in the summer 2015 (EFSA 2015d). In addition it is encouraging that ECDC is leading a similar effort on behalf of all the European Agencies through the EU Agency Network for Scientific Advice (ECDC 2016). This is, however, not enough. What is required now is to have a deeper academically enriched discussion on how to best go forward in the area of uncertainty analysis. We hope that this article has gone some way towards meeting this goal but more is required. What is needed before the EFSA guidance is finalized is an international scientific summit that would firstly, focus on best practices of uncertainty analysis and secondly, examine what should be done on this topic within the European policy arena. Ideally that summit should be held in Brussels in the fall of 2017 and hosted by Commissioner Moedas of DG Research.

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